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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Pero, R. W., *et al.*	
Serial No. 10/718,165	Group Art Unit: 1654
Filed: November 20, 2003	Examiner: **Flood, Michele C.**
For: WATER SOLUBLE COMPOSITIONS DERIVED FROM PLANT MATERIAL AND PREPARATION THEREOF	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

PRE-APPEAL BRIEF REQUEST FOR REVIEW
AND
NOTICE OF APPEAL

In connection with the FINAL action of August 18, 2006 in the prosecution of the above-identified application, the Applicants herein petition the Commissioner for a three month extension of time under 37 CFR § 1.136(a). The Commissioner is duly authorized to charge the proper small entity fees due under § 1.17(a) for the extension, as well as § 41.20(b)(1) for the Notice of Appeal, to Deposit Account No. 50-1943.

The pre-appeal brief request for review begins at page 2 (five (5) pages).
The NOTICE OF APPEAL is attached hereto *as page* 7. +duplicate as Page 9
A TERMINAL DISCLAIMER is attached hereto *as page* 8.

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PRE-APPEAL BRIEF
REASONS FOR REQUEST FOR REVIEW

Claims 1-12 and 14-15 are now pending. No amendments are being filed with this request.

35 USC §112 – Written Description

The Applicants, Dr. Pero, *et al.*, convey in the written description of the invention, with reasonable clarity to those skilled in the art, as of the filing date, *possession* of the invention as claimed, i.e.,

> A process for producing a composition of **water-soluble phytomedicinal compounds** comprising:
>
> combining **green tea** plant material **with water**, in a ratio of plant material to water within a range of about 1:5 to about 1:50, at a temperature between about 75°C and about 102°C for a period of time to solubilize a substantial portion of thermal aqueous extractable phytocompounds present in the plant material, to produce a first extract; and
>
> *removing* substantially all entities having a molecular weight *greater than about 10 kd* from the extract to produce a substantially complete composition of water-soluble phytomedicinal compounds less than about 10kd in size.

The Applicants' written description particularly points out that, "[l]arge molecular weight entities ... are specifically removed to substantially eliminate all entities more than about 10,000 daltons in molecular weight. Particularly, *resulting* water-soluble compositions of the present invention are substantially devoid of molecular entities larger than about 10kd (10,000 daltons Molecular Weight (MW))." Page 3, lines 20-25. *See, also*, e.g., "[t]he water-soluble plant extract is then produced by removal of molecular entities larger than about 10kd, including insoluble particulate materials, for example, by chromatography, filtration, dialysis, or centrifugation." Page 4, lines 18-20. "A myriad of ultra filtration products are available, for example, form Millipore, Billerica, Mass., which have a **10kd cut-off** for use with the present invention." Page 6, line 31- page 7, line 2 (emphasis added). "The efficacy of natural phytochemicals and metabolites are synergized by the novel combinations (compositions **substantially devoid of entities greater than about 10kd**) produced by means of methods of the present invention." Page 10, lines 24-26.

The description must clearly allow persons of ordinary skill in the art to recognize that what is claimed was in fact *conceived* and preferably *reduced to practice*.[1] Indeed, the proscription against the introduction of new matter in a patent application serves to

[1] Moba v. Diamond, 325 F.3d 1306, 66 USPQ2d 1429 (Fed. Cir. 2003); Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052 (Fed. Cir. 2005).

prevent an applicant from adding information that goes beyond the subject matter originally filed. The written description requirement may be satisfied by actual *reduction to practice*, for example, or by disclosure of relevant, identifying characteristics or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed invention. *Guidelines*, 66 Fed. Reg. at 1106.

A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim. In sharp contrast to what the Examiner has stated on the record, the Applicants herein highlight several specific examples that indeed exist "within the four-corners of the as-filed specification" and show *possession* of the subject matter of the claims now pending.

Example I of the specification unequivocally describes an embodiment of the claimed process at page 13 in writing: "Herein provided are details of how to carry out processes of the invention on a large scale. This example is applicable to plant material **to produce preparations substantially devoid of components >10,000 MW**." Page 13, lines 28-30. The exemplified critical size exclusion step is specified in this example as "[u]ltra filtration through HF12". Page 13, line 11. "# 2 Filtration: The extract was ultra-filtered in 3 available units of Koch Romicon HF-12 systems, where each unit had 12 cartridges of Koch Romicon 5 inch diameter HF 66-60 **having exclusion limits of 10,000 molecular weight**. The ultra-filtration capacity was 2000 liters/hour and the filtrated material (i.e. <10,000 molecular weight) was stored in 30 cubic meter stainless steel storage tanks while waiting for final concentration under vacuum." Page 13, lines 38-42.

Example II of the written description states, for example, "[t]his example discloses the spectrum and variety of improvements in phytomedicinal extracts of the present invention by using the method of combining hot water extraction with ultra-filtration to produce extracts characterized as having **about 100% water solubility and compounds of about 10,000d MW or below**." Emphasis added. The Applicants respectfully submit that the written description of the instant application therefore supports the existing limitation of the claims now pending

> ... removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce a substantially complete composition of water-soluble phytomedicinal compounds less than about 10kd in size.

Since the Applicants particularly teach the removal of substantially all entities from the water soluble extracts of green tea that are specifically over 10kd "to produce extracts characterized as having **about 100% water solubility and compounds of about 10,000d MW or below" the Applicants respectfully submit that above identified limitation of**

the claims now pending is supported by written description under 35 USC §112, paragraph 1.

35 USC §112.2 – Indefinite

The Applicants respectfully submit that the language "to produce a substantially complete composition of water-soluble phytomedicinal compounds less than about 10kd in size" is indeed a definite, albeit unnecessary, limitation of the subject matter of the claims now pending. The language of *process* claim 1 specifically requires the *precise step* of ... removing substantially all entities having a molecular weight greater than *about 10kd* from the extract ... The language of the written description, as highlighted *supra*, specifically points to the fact that the disclosed and claimed method of combining hot water extraction with 10 kd cut-off ultra-filtration as described necessarily produces extracts characterized as having about 100% water solubility and compounds of about 10kd and below. As stated in the MPEP § 2173.05(b), Relative Terminology, Acceptability of the claim language depends on *whether one of ordinary skill in the art would understand what is claimed, in light of the specification.* The term "substantially" is often used in conjunction with another term to describe a particular characteristic of the claimed invention. "A claim may be rendered indefinite by reference to an object that is variable." **However, "10 kd" is not a variable reference point.** As is outlined in the MPEP at § 2173.05(b)D, for example, the Applicants respectfully submit that the language "removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce a substantially complete composition of water-soluble phytomedicinal compounds less than about 10kd in size" is plain and definite in view of the instant written description.

35 USC §102 – Anticipation

Anticipation is a question of fact. A patent is invalid if a single prior art reference discloses each and every limitation of the claimed invention either expressly or inherently.[2]

Ishihara

The disclosure of Ishihra, *et al.*, is unequivocally directed to a process of tea extraction which results in compositions particularly enriched in polyphenol compounds including tannins[3] which are less than about 6kd in size.

Ethyl acetate extraction is preferred by Ishihara to enrich the polyphenols,[4] "[t]he solvent used is not particularly limited; water, ethanol, acetone, etc. can be used, singly or in mixture at any ratio ... Concentration can be achieved using an ultrafiltration membrane

[2] SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331 (Fed. Cir. 2005).

[3] Moreover, the instant disclosure teachs the desired removal of tannins and phenolics which tend to aggregate into high molecular weight conjugates. See, e.g., page 3, lines 11-14; lines 27-29.

[4] See, e.g., col.4, lines 36-41, lines 58-63.

or reverse osmosis membrane. These may be used singly or in combination. Also, the purity of polyphenol compounds can be increased by redistributing the obtained extract. In this case, it is preferable to use a water-ethyl acetate system for distribution; polyphenol compounds are concentrated in the ethyl acetate fraction." Col.6, line 55 – col. 7, line 10. Particularly, "[m]ore specifically ... the obtained extract is concentrated using an ultrafiltration membrane of a fractional molecular weight of 3,000 to 6,000, followed by further concentration ... with ethyl acetate, and the obtained ethyl acetate layer is removed."[5]

However, the Applicants respectfully point out that 10 kd is not equal to 6 kd (not even for large values of 6 kd).[6,7] Entities that are about 10 kd *unequivocally* do not overlap with entities that are about 6 kd. Therefore, compositions specifically produced by the step of "removing substantially all entities having a molecular weight greater than about 10 kd from the extract" differ significantly from compositions produced by a step of specifically removing substantially all entities having a molecular weight greater than about 6 kd from the extract. In other word the steps are distinct, each of which necessarily yield distinct products. The steps to yield specific compositions of **water-soluble phytomedicinal compounds**, required by the pending instant claims, i.e., "to produce a substantially complete composition of water-soluble phytomedicinal compounds less than about 10 kd in size", are specific and are distinct from anything described, contemplated or suggested within the disclosure of Ishihara.

To establish anticipation, the reference must meet the limitations of the now pending claims. However, as discussed herein, for example, Since the disclosure of Ishihara does not teach the unequivocal limitations of the now pending claims, Ishihara cannot anticipate.

35 USC §103 – Obviousness

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations.[8] Moreover, even if all the limitations previously existed, it is axiomatic that a claimed invention is not obvious solely because it is composed of elements that are all individually found in the prior art.

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[5] Example II describes a 6000 fractional molecular weight filtration.

[6] Neither is10 kd equal to 3 kd.

[7] The instant claims require a specific water extraction process for producing a substantially complete composition of water-soluble compounds from green tea that are specifically less than about 10kd in size. In other words the "cutoff" is specific. 10 kd is not an arbitrary exclusion size. 10 kd is an expressly critical limitation of the claimed process and is indeed distinct from the 6kd. exclusion size contemplated by Ishihara.

[8] See, e.g., In re Rouffet, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457 (Fed. Cir. 1998). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Id. However, neither of the references relied upon by the Examiner in this case, i.e., Ishihara and Lunder, teach independently or in combination, the *specific* step of "removing substantially all entities having a molecular weight greater than about 10kd from the extract". As pointed out in the specification 10 kd is the critical size exclusion "cutoff". The steps of the process of the present invention is so limited. Since neither Ishihara or Lunder, alone or in combination, teach the express size exclusion limitation of the process claims now pending to produce "a substantially complete composition of water-soluble phytomedicinal compounds less than about 10kd in size", the current subject matter specifically recited in the now pending claims, and distinct from anything described, contemplated or suggested within the disclosure of Ishihara or Lunder, cannot be obvious as a matter of law.

Conclusory statements do not suffice. This factual question is material to patentability, and cannot be resolved on subjective belief and unknown authority. It is improper, in determining the value and novelty of the specific 10 kd size of exclusion simply to use that which the inventor taught against its teacher. Conclusory statements such as those here provided do not fulfill the agency's obligation. *See*, Zurko, 258 F.3d at 1385, 59 USPQ2d at 1697, that "deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense'."

Terminal Disclaimer

To address the Double Patenting rejection the Applicants include herewith a properly executed Terminal Disclaimer under 37 CFR 1.321(c) with regard to copending application Ser. No. 11/081,296.[9]

The Commissioner is further authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

Respectfully submitted,

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[9] It is the intention of the Applicants to expedite the prosecution of the instant case without prejudice to the copending application.